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September 4, 2024

VIA ECF

Honorable Cathy L. Waldor, U.S.M.J.
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, NJ 07102

Re: *American Regent, Inc. v. Accord Healthcare, Inc., No. 2:24-cv-07791 (BRM) (CLW)*
American Regent, Inc. v. Aspiro Pharma Ltd., No. 2:24-cv-07794 (BRM) (CLW)
American Regent, Inc. v. Cipla USA, Inc. et al., No. 2:24-cv-07796 (BRM) (CLW)
American Regent, Inc. v. Dr. Reddy's Lab'y's, Inc., et al., No. 2:24-cv-07799 (BRM) (CLW)
American Regent, Inc. v. Fresenius Kabi USA, LLC, No. 2:24-cv-07801 (BRM) (CLW)
American Regent, Inc. v. Gland Pharma Ltd., No. 2:24-cv-7802 (BRM) (CLW)
American Regent, Inc. v. Hikma Pharms. USA, Inc., No. 2:24-cv-7803 (BRM) (CLW)
American Regent, Inc. v. Long Grove Pharms., LLC, No. 2:24-cv-7804 (BRM) (CLW)
American Regent, Inc. v. RK Pharma Inc., No. 2:24-cv-7805 (BRM) (CLW)
American Regent, Inc. v. Somerset Therapeutics, LLC, et al., No. 2:24-cv-7807 (BRM) (CLW)
American Regent, Inc. v. Steriscience Pte. Ltd., No. 2:24-cv-7809 (BRM) (CLW)
American Regent, Inc. v. Sun Pharm. Indus. Ltd., et al., No. 2:24-cv-7810 (BRM) (CLW)
American Regent, Inc. v. Xiromed, LLC, et al., No. 2:24-cv-7811 (BRM) (CLW)
American Regent, Inc. v. Zydus Pharms. (USA) Inc., No. 2:24-cv-7812 (BRM) (CLW)

Dear Judge Waldor:

We, along with Sterne, Kessler, Goldstein & Fox P.L.L.C., represent Plaintiff American Regent, Inc. ("ARI") in the above-referenced matters. These 14 matters are all Hatch-Waxman cases concerning the patent covering ARI's Selenius Acid products. We write in advance of the currently scheduled September 9, 2024 Zoom conference in the *ARI v. Xiromed, LLC, et al.*, No. 24-7811 (August 14, 2024 docket entry) and *ARI v. Zydus Pharms. (USA) Inc.*, No. 24-7812 (ECF No. 11) matters to bring to the Court's attention certain preliminary scheduling issues that affect all of the above-referenced cases.

With respect to the schedule, it is unclear whether there is a 30-month regulatory stay available for these cases. Thus, ARI intends to seek an expedited schedule. Plaintiff's proposed schedule is attached as Exhibit A. ARI has provided the proposed schedule to all Defendants in the above-referenced cases and they are currently considering the proposal. Defendants have advised ARI that they intend to provide a response to the expedited scheduling proposal once they have had an opportunity to confer with their clients and consider potential issues that will need to be dealt with through potential coordination and/or consolidation, including: (1) the existence of another related matter filed in the District of Delaware currently before the Judicial

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Panel on Multidistrict Litigation (MDL No. 3129); (2) the fact that the patent at issue in this matter is currently being litigated before this Court in Civil Action No. 2:24-cv-01022-BRM-CLW, which already has a schedule in place; and (3) Plaintiff's claim that there may be a 30-month regulatory stay available for these cases.

Given the related nature of all of the above-referenced cases and to preserve the Court's and the parties' resources, ARI respectfully requests that all of the Defendants in the remaining related cases be added to the September 9, 2024 Zoom conference to discuss the schedule and possible consolidation of the cases¹. So far counsel for Accord Healthcare, Inc., the Somerset Defendants, the Cipla Defendants, the DRL Defendants, Hikma Pharms. USA, Inc., Gland Pharma Ltd., Long Grove Pharmaceuticals, LLC, the Sun Defendants, RK Pharma, Inc., and Aspiro Pharma Ltd. have expressed a willingness to participate in the September 9, 2024 Zoom conference. Though we have not yet received responses from all other Defendants, we assume they would also like to participate.

Additionally, ARI has received a notice letter from a 15th ANDA filer, Eugia Pharma Specialities Limited. Should the Court wish to include Eugia, ARI will likely file a complaint in that matter this week and before the September 9, 2024 Zoom conference.

We thank the Court for its consideration and assistance in this matter. We look forward to discussing these issues with Your Honor during the September 9, 2024 Zoom conference.

Respectfully submitted,

s/ Charles H. Chevalier
Charles H. Chevalier

cc: All counsel of record in all of the above-referenced matters via ECF and e-mail

¹ Pursuant to Judge Martinotti's Judicial Preferences, Defendant Fresenius Kabi USA, LLC ("FK") filed a pre-motion letter yesterday seeking leave to file a motion to dismiss for lack of venue (ECF No. 12 in 24 CV 7801). As such, FK would prefer to hold off participating in the Court conference at this time, pending resolution of FK's pre-motion letter request. FK will, of course, join the call if the Court requires FK's attendance.